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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,631	07/02/2003	Charles C. Hart	A-2202-AL	3645

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,631

Applicant(s)

HART ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-29 is/are allowed.
- 6) ☒ Claim(s) 1-13 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 1 August 2006.
2. Examiner confirms the restriction requirement of Species 1 directed to Figures 2-17 and Claims 1-13 and that one other species, Species 2 is directed to Figures 18-22 and Claims 14-21.
3. Examiner acknowledges the amendments and the corrections made to the specification.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9, 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Toso et al.** (U.S. Patent No. **5,282,832**) in view of **Bonutti et al.** (U.S. Pub. No. **20050267534**).

Claims 1 and 2: Toso et al. discloses a suture clip with a first interlocking member **110** and a second interlocking member **120** which is operable of mating with the first interlocking member **110** (Figure 1 and col. 2, lines 53-56). The interlocking members **110** and **120** provide a first position for capturing the suture ends (col. 3, lines 44-45). A

second position is also provided by the members for guiding and aligning the suture ends along a tortuous path within and between the interlocking members **110** and **120**, as well as a third position that allows for frictionally engaging the suture ends to provide secure entrapment of the suture (col. 3, lines 43-58). Toso et al. discloses the first interlocking member **110** having a "standing portion" consisting of **112** and **113** that engages with "mating window" **121** disposed in the second interlocking member **120**. Although Toso et al. discloses the limitations in one interlocking member, he does not disclose the limitations of at least one protrusion, at least one mating well, a standing portion, and a mating window for each of the interlocking members. It would have been obvious to one of ordinary skill in the art to provide these limitations on each of the two interlocking members of the device of Toso et al. for secure engagement of the two connecting elements.

Also not claimed by Toso et al. is the protrusions being cylindrical and sized to match opposing mating holes. Bonutti et al. discloses a suture retainer with cylindrical protrusions **360**, **362**, **364**, and **366**, which are fixedly connected with rectangular end walls (Figure 20 and page 12, paragraph 157). Bonutti et al. teaches that the bends formed in the suture around the cylindrical protrusions are free of abrupt stress inducing discontinuities (page 12, paragraph 164). It would have been obvious to one of ordinary skill in the art at the time of invention to provide cylindrical protrusions, as taught by Bonutti et al., to the device of Toso et al., in order to form bends lacking stress inducing discontinuities. Although opposing mating holes are not located opposite the cylindrical protrusions in Bonutti et al., but rather fixed connections to opposite end walls, it would

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have been obvious to one of ordinary skill to provide an opposing mating hole to the protrusions since it was known in the art that protrusions of one member readily engage with holes or apertures of another member within two connecting members. It would have been obvious to one of ordinary skill in the art to provide protrusions, as taught by Bonutti et al. and corresponding mating holes for secure engagement of the two interlocking members.

Claim 3: Toso et al. discloses the standing portion consisting of **112** and **113**, which could also be considered as protrusion elements, that have barbs **115** and **116** to engage with the mating window **121**, which could also be considered as a mating hole (Figure 2). The barbs **115** and **116** could be applied to the cylindrical protrusions of Bonutti et al.

Claims 4-5: Toso et al. discloses the mating window **121** sized and configured to receive the opposing standing portion consisting of **112** and **113**, as well as the suture ends **130** (Figure 1).

Claim 6: Toso et al. lacks the limitation of the assembly of the interlocking members being able to be advanced, retracted or adjusted along the length of the suture. Bonutti et al. discloses the suture retainer being able to move along sections of a suture (page 12, paragraph 161).

Claims 7-8: Toso et al. discloses the standing portion consisting of **112** and **113** with locking barbs **115** and **116** that are snap fit with the receiving portion of second interlocking member **120** (col. 3, lines 6-11).

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Claim 9: Toso et al. discloses the suture clip being made out of plastics of the same genus as the suture, such as bioabsorbable polymeric material (col. 2, lines 57-62).

Claims 22-23 (New): Toso et al. discloses the claimed structure except for the barbs or increased end diameters, as well as the locking or latching features of the standing portions, are in a non-contacting relationship with the suture.

Bonutti et al. teaches barbs or increased end diameters and the locking or latching features of the standing portions that are in a non-contacting relationship with the suture (Figure 20). It would have been obvious to one of ordinary skill in the art at the time of invention to provide barbs and the locking or latching features of the standing portions that are in a non-contacting relationship with the suture, as taught by Bonutti et al., to Toso et al., in order to maintain smooth continuous bends and to avoid stress-inducing discontinuities (page 12, paragraph 159).

Claim 25 (New): Toso et al. discloses the first interlocking member having a first length and a first width and the second interlocking member having a second length and a second width, the second length corresponding to the first length and the second width corresponding to the first width (Figure 1).

3. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Toso et al.** (U.S. Patent No. **5,282,832**) and **Bonutti et al.** (U.S. Pub. No. **20050267534**) as applied to Claim 1 above, and further in view of **Wenstrom, Jr. et al.** (U.S. Patent No. **6,045,573**).

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Claims 10-13: Toso et al. and Bonutti et al. disclose the claimed device except for the interlocking members being formed of metal, including stainless steel, titanium, silver, gold, and aluminum. Both references also disclose the claimed device except for the metal being malleable and the interlocking members being formed of plastic and metal. Wenstrom, Jr. et al. discloses a suture anchor, or a member having a suture mounted thereto, which can be made of materials such as stainless steel, titanium, gold, and equivalents thereof (such as silver and aluminum) that are non-absorbable materials. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the metal material including stainless steel, titanium, silver, gold and aluminum, as taught by Wenstrom, Jr. et al., to the combined device of Toso et al., Bonutti et al., in order to provide a non-absorbable material for use with sutures. Furthermore, one skilled in the art would use well-known materials, such as any suitable metal or non-metal material (plastic), or combination thereof, to form the interlocking members in the combined device of Toso et al. and Bonutti et al. since they would yield well-known properties such as being bio-absorbable or malleable, which is helpful in accommodating movement and is bendable.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Toso et al.** (U.S. Patent No. **5,282,832**) and **Bonutti et al.** (U.S. Pub. No. **20050267534**), as applied to Claim 1 above, and further in view of **Christensen** (U.S. Patent No. **4,592,116**).

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Claim 24 (New): Toso et al. and Bonutti et al. disclose the claimed invention, including the standing portions of one of the first interlocking member and the second interlocking member being extendable through the mating window of one of the first interlocking member and the second interlocking member (see paragraph 2 above), except for the standing portions of one of the first interlocking member and the second interlocking member being foldable onto an exterior surface of one of the first interlocking member and the second interlocking member away from the suture.

Christensen teaches one of the standing portion of one of a first interlocking member and a second interlocking member being foldable onto an exterior surface of one of the first interlocking member and the second interlocking member away from the suture (Figures 4 and 5). It would have been obvious to one of ordinary skill in the art to provide a foldable standing portion of an interlocking member, as taught by Christensen, to Toso et al. and Bonutti et al. since it was known in the art that foldable or bendable portion of an interlocking member provides better security for clinches.

Allowable Subject Matter

5. Claims 26, 27, 28, and 29 are allowed over the prior art.

The following is an examiner's statement of reasons for allowance:

None of the prior art of record, alone or in combination, discloses a first interlocking member with the combination of elements including a standing portion, a protrusion, which is smaller than the standing portion, a mating window, and a mating hole, which is smaller than a mating window, in the claimed configuration, such as being

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all disposed on both interlocking members. Prior art of record do disclose protrusions, or standing portions, and mating windows, or mating holes, on interlocking members, yet lack the present invention's number, size, and configuration of the elements on both interlocking members,

Response to Arguments

6. Applicant's arguments filed 1 August 2006 have been fully considered but they are not persuasive.

Applicant argues that the action and Toso (Toso et al.) are silent as to the claim elements of at least one protrusion and at least one mating hole as recited in Claim 1. The examiner disagrees. The Toso reference is meant to be combined with the Bonutti (Bonutti et al.) reference. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The applicant generally argues that there is not any teaching, suggestion, or motivation to modify Toso to provide just one member having all four elements recited in Claim 1 or even two members. However, these limitations are obvious to one of ordinary skill in the art, as maintained above, in that two connecting elements may possess as many of each of the standing portions and/or protrusions and the mating windows and/or mating holes in each and/or both of the two

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connecting elements depending on the desired amount of security or the strength of the bond of the connecting elements.

Applicant also argues that Toso does not describe the "second position" as recited in Claim 1. The examiner disagrees. As maintained above, the suture threadlines are "positioned transversely over and across" the first and second interlocking members as seen in Figure 1, and the suture ends are capable of being guided and aligned to a preferred location along a tortuous path within and between the first and second interlocking members in this disclosed configuration.

Applicant argues that there are contradictory teachings in Toso and Bonutti regarding the cylindrical protrusions and friction and stress inducing forces. The examiner disagrees. Toso teaches that friction is developed at each of the bends that the suture is subjected to in the suture clip while Bonutti describes smooth, continuous bends free of stress inducing discontinuities in the suture when placed in the suture fastener. Bonutti does not teach sutures that are free from friction and retentive forces, but rather lack discontinuities that would subject the sutures to higher stress (force divided by area), such as with abrupt, sharp square-shaped protrusions, as opposed to the cylindrical protrusions. Therefore, the Toso and Bonutti teachings are not contradictory, but rather there is a motivation to combine the two because of the need for both friction and retentive forces, and smooth, continuous bends.

Applicant argues that it is contradictory to discard the teaching of Bonutti to fixedly connect the cylinders to the end walls of a housing enclosing cylinders to a non-fixed connection and a non-enclosed housing of Toso's two separable members. The

examiner disagrees. Toso teaches in Figure 1 a mating hole **121**, which may also be considered a mating window. It is obvious to one of ordinary skill in the art, as maintained above, to provide an opposing mating hole to a protrusion in connecting members.

Applicant also argues that the action and Toso are silent as to why legs **112** and **113** of Toso could also be considered as the two separate elements of a standing portion and at least one protrusion. The examiner maintains that as claimed, the "standing portion" element is equivalent to a "protrusion" element, and a "mating window" element is equivalent to a "mating hole" element, and it is obvious to one of ordinary skill in the art to provide all of each on one connecting member or both connecting members or a multiple of each element on either connecting member, as maintained above.

Applicant argues that allowing the assembly of member **110** and **120** in Toso to be advanced, retracted, or adjusted would contradict Toso's teaching of being "securely held in serpentine configuration" as stated in col. 3, lines 56-58. However, the examiner disagrees. Toso's "securely held" suture does not necessarily imply being incapable of adjustment when a pulling force is applied, but rather does not easily slip or slide out of the suture fastener when in a static position or when no forces are being applied to the suture. Also on page 12, paragraph 161 of Bonutti, as maintained above, the suture retainer is moved along sections of the suture, with the teaching of being able to be moved towards the body tissue. Therefore there is motivation to combine Bonutti and Toso regarding this limitation.

Applicant argues that Wenstrom (Wenstrom Jr. et al.) does not suggest features recited in Claims 12-13 nor provides any teachings, suggestion or motivation to combine with Toso and Bonutti. The examiner disagrees and maintains that it would have been obvious to one of ordinary skill to provide materials such as malleable metal and plastic to form interlocking members because of their biocompatible properties. Wenstrom's suture anchor being metal that is malleable would not make it inoperable, since there are degrees of malleability and stainless steel will deform under a certain amount of force, rather than fracture, as non-malleable or non-ductile materials do.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER